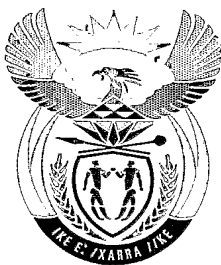


Sertifikaat

REPUBLIEK VAN SUID AFRIKA

PATENT KANTOOR
DEPARTEMENT VAN HANDEL
EN NYWERHEID*Certificate*

REPUBLIC OF SOUTH AFRICA

PATENT OFFICE
DEPARTMENT OF TRADE AND
INDUSTRYHiermee word gesertifiseer dat
This is to certify that

REC'D 08 NOV 2004

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the documents attached hereto are true copies of Forms P1, P2
and provisional specification and drawings of South African Patent Application
No. 2004/1530 in the name of South African Medical Research Council
Carotino SDN BHD

Filed : 25 February 2004

Entitled : Food Product

Geteken te
PRETORIA
Signed atin die Republiek van Suid-Afrika, hierdie
in the Republic of South Africa, this18th dag van
August 2004
day of

Registrar of Patents

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

REPUBLIC OF SOUTH AFRICA			REGISTER OF PATENTS			PATENTS ACT, 1978		
OFFICIAL APPLICATION			LODGING DATE: PROVISIONAL			ACCEPTANCE DATE		
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INTERNATIONAL CLASSIFICATION			LODGING DATE: COMPLETE			GRANTED DATE		
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FULL NAME(S) OF APPLICANT(S)/PATENTEE(S)								
71	SOUTH AFRICAN MEDICAL RESEARCH COUNCIL CAROTINO SDN BHD							
APPLICANTS SUBSTITUTED:						DATE REGISTERED		
71								
ASSIGNEE(S)						DATE REGISTERED		
71								
FULL NAME(S) OF INVENTOR(S)								
72	BENADE, SPINNLER							
PRIORITY CLAIMED			COUNTRY		NUMBER		DATE	
N.B. Use International abbreviation for country (see Schedule 4)			33	NIL	31	NIL	32	NIL
TITLE OF INVENTION								
54	FOOD PRODUCT							
ADDRESS OF APPLICANT(S)/PATENTEE(S)								
1. FRANCIE VAN ZIJL DRIVE, PAROW, 7505, WESTERN CAPE, SOUTH AFRICA 2. PLOT 519, JALAN BESI SATU, PAIR GUDANG INDUSTRIAL ESTATE, PASIRE GUDANG, 81700, DARUL TAKZIM, JOHOR, MALAYSIA								
ADDRESS FOR SERVICE						S & F REF		
74	SPOOR & FISHER, SANDTON					PA136720/P		
PATENT OF ADDITION NO.				DATE OF ANY CHANGE				
61								
FRESH APPLICATION BASED ON				DATE OF ANY CHANGE				

APPLICATION FOR A PATENTAND ACKNOWLEDGEMENT OF RECEIPT 25.02.04
(Section 30 (1) – Regulation 22)**R 006000**

The granting of a patent is hereby requested by the undermentioned applicant on the basis of the present application filed in duplicate

HASR 711

INCOME TAX

REPUBLIC OF SOUTH AFRICA
S & F REFERENCE

OFFICIAL APPLICATION NO.

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FULL NAME(S) OF APPLICANT(S)

71 1. SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
2. CAROTINO SDN BHD

ADDRESS(ES) OF APPLICANT(S)

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TITLE OF INVENTION

54 FOOD PRODUCT

THE APPLICANT CLAIMS PRIORITY AS SET OUT ON THE ACCOMPANYING FORM P.2. THE EARLIEST PRIORITY CLAIM IS:

COUNTRY: NIL NUMBER: NIL DATE: NIL

THIS APPLICATION IS FOR A PATENT OF ADDITION TO PATENT APPLICATION NO.

21 01

THIS APPLICATION IS A FRESH APPLICATION IN TERMS OF SECTION 37 AND IS BASED ON APPLICATION NO.

21 01


THIS APPLICATION IS ACCOMPANIED BY:

- ☒ 1. A single copy of a provisional specification of 15 pages.
- ☐ 2. Drawings of sheets
- ☐ 3. Publication particulars and abstract (Form P.8 in duplicate).
- ☐ 4. A copy of Figure of the drawings (if any) for the abstract.
- ☐ 5. Assignment of invention.
- ☐ 6. Certified priority document.
- ☐ 7. Translation of the priority document.
- ☐ 8. Assignment of priority rights.
- ☐ 9. A copy of the Form P.2 and the specification of S.A. Patent Application No.
- ☐ 10. Declaration and power of attorney on Form P.3.
- ☐ 11. Request for ante-dating on Form P.4.
- ☐ 12. Request for classification on Form P.9.
- ☒ 13. Form P.2 in duplicate.
- ☐ 14. Other.

74 ADDRESS FOR SERVICE: SPOOR & FISHER, SANDTON

REGISTRAR OF PATENTS DESIGNS,
TRADE MARKS AND COPYRIGHT

Dated: 25 February 2004

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 SPOOR & FISHER
 PATENT ATTORNEYS FOR THE APPLICANT(S)

REGISTRAR OF PATENTS

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978**PROVISIONAL SPECIFICATION**

(Section 30(1) – Regulation 27)

OFFICIAL APPLICATION NO.

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FULL NAMES OF APPLICANTS

71	SOUTH AFRICAN MEDICAL RESEARCH COUNCIL CAROTINO SDN BHD
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FULL NAMES OF INVENTORS

72	BENADE, SPINNLER
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TITLE OF INVENTION

54	FOOD PRODUCT
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BACKGROUND OF THE INVENTION

20 The present invention relates to a food product enriched with micronutrients, in particular a spreadable food product.

25 Populations in certain developing countries are known to suffer from specific vitamin and/or mineral (micronutrients) deficiencies, mainly because of a low dietary intake of these nutrients. These deficiencies are known to impact negatively on the health, growth and development of children. Increased susceptibility to infections as a result of these micronutrient deficiencies in school learners may also lead to lower school attendance rates, impaired mental ability and consequently compromised school performance. Addressing these deficiencies in school learners has proved to have beneficial effects on the nutritional status, health, school attendance and mental abilities of the learners. Although there are several strategies for addressing these deficiencies, the food-based approach is generally accepted as the most sustainable one.

30

Micronutrient deficiencies among school learners in certain developing countries should be a cause of great concern. Although a school feeding scheme was introduced in South Africa, the main objective of the scheme was to provide about 25% of the energy requirements of the learners. No special attempt was made to address the micronutrient deficiencies which are known to exist in these learners. Several menus were formulated and one menu specifically prescribed bread and peanut butter as an option.

Bread and peanut butter have become a popular choice of many schools. There are, however, many disadvantages associated with this peanut butter and bread menu. In South Africa, peanut butter is often contaminated with aflatoxin, which poses serious health risks to the consumer. Also, where micronutrient deficiencies exist, peanut butter consumption has no impact on micronutrient deficiencies in learners.

The applicants have therefore identified a need for a safe food product that is relatively inexpensive to produce and that addresses the nutritional needs of children in particular, by providing not only a source of energy but also a safe source of micronutrients and vitamins.

SUMMARY OF THE INVENTION

According to a first aspect of the invention, there is provided a food product having a composition including:

- a high protein food source;
- a fat, oil or mixture thereof; and
- at least one micronutrient.

The food product may be a spreadable food product, for example, a paste.

The micronutrient may be substantially micro-encapsulated by the fat and/or oil in the food product.

5 The product may further include one or more vitamins, such as vitamins A, C, and/or E; a sweetening agent and/or energy source, such as sugar or a sugar syrup; and a flavouring agent.

The high protein source may be a high-protein flour, such as soy flour.

10 The fat and/or oil may be rich in carotenoids, tocopherols and/or tocotrienols. For example, the fat and/or oil may be CarotinoTM CS35FV.

15 The sugar syrup may be invert or partial invert syrup, and typically has a water content of between 15 wt % to 25 wt %. The sugar syrup is preferably Puratex 78150.

The source of Vitamin C may be ascorbic acid, sodium ascorbate or potassium ascorbate.

20 The micronutrients may include a source of iron, zinc or selenium, or a mixture thereof.

25 The source of iron may be one or more compounds selected from the group consisting of ferrous fumarate, ferrous gluconate, ferrous phosphate, ferrous sulphate, elemental iron or electrolytic iron, ferric pyrophosphate, ferric ammonium citrate, ferric orthophosphate, Na Fe EDTA, ferrous lactate, ferrous succinate and ferrous saccharate.

30 The source of zinc may be one or more compounds selected from the group consisting of zinc amino acid chelate, zinc gluconate, zinc oxide, zinc sulphate, zinc undecylenate, zinc chloride, zinc stearate and zinc acetate.

The source of selenium may be one or more compounds selected from the group consisting of selenium yeast, selenium sulfide, selenium amino acid chelate, selenium oxide, sodium selenite and sodium selenate.

- 5 The food product preferably includes the micronutrients ferrous fumarate, zinc amino acid chelate and selenium amino acid chelate.

The overall water content in the food product may be below 7 wt %. Preferably, the overall water content in the food product is about 6 wt %.

10

Typically, the composition of the food product includes:

- a) $64,50 \pm 35$ wt % of the fat and/or oil;
- b) $15,48 \pm 15$ wt % of the high protein food source;
- c) $0,03 - 0,66$ wt % of micronutrients;
- 15 d) $0,02 - 0,30$ wt % of the vitamin;
- e) $19,35 \pm 19$ wt % of the sweetening agent and/or energy source; and
- f) $0,10 - 0,30$ wt % of the flavouring agent.

20

Typically, the micronutrients include 18,59 wt % of iron fumarate, 61,06 wt % of zinc amino acid chelate and 20,35 wt % of selenium amino acid chelate.

The content of the vitamin(s) is preferably 0,15 wt %, and the content of the flavouring agent(s) is preferably 0,19 wt %.

25

Preferably, 100 g of the food product composition includes:

- a) $68,5 \text{ g} \pm 35\%$ of the fat and/or oil;
- b) $6,5 \text{ g} \pm 15\%$ of the protein food source;
- c) $17,6 \text{ g} \pm 19\%$ of a carbohydrate;
- d) $7 - 75$ mg of a source of iron;
- 30 e) $6,9 - 70$ mg of a source of zinc;
- f) $26 - 266$ μg of a source of selenium;
- g) $15 - 300$ mg of ascorbic acid;

- h) 80 – 250 mg of a flavouring agent;
- i) 32 mg \pm 10% of carotenoids;
- j) 32 mg \pm 10% of tocopherols and/or tocotrienols;
- k) 50 mg \pm 10% of isoflavones, and
- 5 l) 6 g \pm 10% of moisture.

According to a second aspect of the invention, there is provided a method of making a food product which includes the steps of:

- 10 a) mixing at least one micronutrient with a first portion of a high protein food source to form mixture (a);
- b) adding a fat and/or oil to mixture (a) and mixing them together to form a combined mixture (b);
- c) adding the combined mixture (b) to a second portion of a high protein food source to form the food product; and
- 15 d) optionally adding a sweetening agent, a vitamin and a flavouring agent to the food product.

The micronutrient, high protein food source, fat, oil, sweetening agent and/or energy source, and/or flavouring agent may be substantially as described above.

20

DETAILED DESCRIPTION OF THE INVENTION

The invention describes a food product having a composition which includes a high protein food source, a fat or an oil or a mixture thereof, and at least one micronutrient. Optionally, the food product also includes one or more essential water-soluble micronutrients, such as iron, zinc and selenium. The food product may further include one or more vitamins, such as vitamins A, C and/or E. The vitamins may also have the benefit of being antioxidants. Additionally, the food product may also include a sweetening agent and/or energy source, carbohydrates and/or isoflavones.

The formation of a fat-based food product which includes water-soluble ingredients is made possible by the mixing sequence and technique. The micronutrients are substantially micro-encapsulated by the fat or oil, which protects them against oxidation and interaction with the vitamin C, thereby rendering the product stable and resistant to rancidity and fungal growth.

The food product has a low water content, and this, together with the blending sequence, results in a food product comprising a fat medium containing relatively high levels of antioxidants (tocopherols, tocotrienols, carotenoids and vitamin C) with micronutrients dispersed therein.

The high protein food source is generally high protein flour such as soy flour, but may be any other suitable high protein source.

The sweetening agent and/or energy source is generally a sugar in the form of a syrup, for example, an invert or partial invert syrup. Partial invert syrup is used in baking, confectionery, pharmaceutical and ice cream manufacturing. It is manufactured by a known process of acid inversion of refined sugar and followed by neutralisation of the sugar. The ratio of invert sugar to sucrose is about 2:1. Generally, any sweetening agent or energy source with a water content of between 15 wt % and 25 wt % will be suitable.

A flavouring may also be added to the food product. The flavouring is any standard flavouring used in the food industry. It can be an oil, water or fat-soluble concentrate. Examples of flavours are banana, vanilla and chocolate.

The overall water content in the food product is generally below 7 wt %. For example, the food product in the example discussed herein has an overall water content of about 6.01%.

Apart from providing energy, the food product also provides a significant daily allowance of iron, zinc, selenium, vitamin C, vitamin A and vitamin E to those who ingest the product, in particular school learners, thus alleviating these deficiencies.

- 5 The following example will now be used to further illustrate the invention.

Example 1

- 10 Micronutrients used in the examples to illustrate the present invention are selected from sources of iron, zinc and selenium listed in Table 1.

TABLE 1

Iron	Zinc	Selenium
Ferrous fumerate	Zinc amino acid chelate	Selenium yeast
Ferrous gluconate	Zinc gluconate	Selenium sulfide
Ferrous phosphate	Zinc oxide	Selenium amino acid
Ferrous sulphate	Zinc sulphate	chelate
Elemental iron / electrolytic iron	Zinc undecylenate	Selenium oxide
Ferric pyrophosphate	Zinc chloride	Sodium selenite
Ferric ammonium citrate	Zinc stearate	Sodium selenate
Ferric orthophosphate	Zinc acetate	
Na Fe EDTA		
Ferrous lactate		
Ferrous succinate		
Ferrous saccharate		

- 15 The fat or oil used in the example is CarotinoTM fat CS35FV, manufactured by Caratino Sdn Bhd of Malaysia. This fat or oil is rich in carotenoids, tocopherols or tocotrienols (vitamin E). CarotinoTM fat CS35FV is manufactured from crude palm oil and refined according to a process described in US Patent Number 5,932,261, the disclosure of which is incorporated by reference herein.

Carotino™ fat CS35FV contains a wide spectrum of carotenoids, tocopherols and/or tocotrienols. Alpha-carotene and beta-carotene are the main carotenoids in Carotino™ fat CS35FV, constituting 91% of the total carotenoids. The carotene composition of Carotino™ fat CS35FV is shown in Table 2.

TABLE 2

Carotene	Composition (%)	PPM
Phytoene	2.0	10.0
Phytofluene	1.2	6.0
Cis-beta-carotene	0.8	4.0
Beta-carotene	47.4	237.0
Alpha-carotene	37.0	185.0
Cis-alpha-carotene	6.9	34.5
Gamma-carotene	1.3	6.5
Zeta-carotene	0.5	2.5
Delta-carotene	0.6	3.0
Neurosporene	trace	-
Beta-Zeacarotene	0.5	2.5
Alpha-Zeacarotene	0.3	1.5
Lycopene	1.5	7.5
Total (ppm)		500.0
Typical range of total carotene content (ppm)		250 - 700

Values provided by Carotino Sdn Bhd

10 The vitamin E composition of Carotino™ fat CS35FV is shown in Table 3.

TABLE 3

Vitamin E	Composition (%)	PPM
Tocopherols	20 - 30	80 – 240
Tocotrienols	70 - 80	280 – 640

Total (ppm)	360 – 880
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Values provided by Carotino Sdn Bhd

The high protein food in the food product is a protein-rich soy flour. The soy flour used in the invention is cooked or roasted soy flour, preferably medium roast soy flour.

Puratex™ 78150, a product of Tongaat-Hulett Sugar Ltd, RSA, is a partial invert syrup which is used in the example. The standard specification of Puratex 78150 is provided in Table 4.

TABLE 4

Specification	Unit	Measurement
True dissolved solvents	%	77,7-78,3
Dissolved solids (Measured using refractometer)		76,5-77,1
Level of inversion	%	48,0-51,0
pH		4,5-5,5
Colour	IU	120 max
Ash (conductivity)	%	0,1 max
Sulphite as SO ₂	ppm	70 max

The food product of the invention is made by using the following :

- i) Carotino™ fat CS35FV,
- ii) soy flour,
- iii) Puratex™ 78150,
- iv) micronutrient premix containing iron fumerate, zinc amino acid chelate and selenium amino acid chelate,
- v) ascorbic acid, and
- vi) any flavouring agent.

An example of the composition of the spreadable food product is shown in Table 5. This composition includes a micronutrient premix referred to in (iv) above. The ratio of iron fumerate, zinc amino acid chelate and selenium amino acid chelate is shown in Table 6.

5

TABLE 5

Ingredient	Composition (weight %)	Range (weight %)
Carotino™ fat CS35FV ^a	64,50	±35
Soy flour (medium roast) ^b	15,48	±15
Puratex™ 78150 ^c	19,35	±19
Micronutrient Premix	0,33	0,03 – 0,66
Ascorbic acid ^d	0,15	0,02 – 0,30
Flavouring agent ^e	0,19	0,10 – 0,30
Total	100,00	

^a Carotino Sdn Bhd, Malaysia

^b Pioneer Foods (Pty) Ltd, RSA

^c Tongaat-Hulett Sugar Ltd, RSA

^d Warren Chem Specialities, RSA

^e International Flavours and Fragrances (SA) (Pty) Ltd, RSA

10

TABLE 6

Ingredient	Composition (weight %)	Range (weight %)
Iron fumerate ^a as a source of iron	18,59	0-100
Zinc amino acid chelate 10% (tasteless) ^b as a source of zinc	61,06	0-100
Selenium amino acid chelate 0.2% ^c as a source of selenium	20,35	0-100
Total	100,00	

^aBP 2001, USA 25 Warren Chem Specialities

^bProduct ZNC 271, AMT Labs Inc, food grade

^cProduct SEA 221, AMT Labs Inc

15

An example of a nutritional composition of the food product per 100 g is shown in Table 7.

5

TABLE 7

Nutrient	Weight	Range
Fat	68,53 g	±35%
Protein	6,51 g	±15%
Carbohydrate	17,62 g	±19%
Iron	21,08 mg	7,03 – 70,20
Zinc*	20,74 mg	6,90 – 69,06
Selenium*	133,00 µg	26,60 – 266,00
Ascorbic acid	150,00 mg	15 – 300
Flavouring agent	190,00 mg	180 – 250
Total carotenoids	32,26 mg	±10%
Total tocopherol and/or tocotrienol	32,26 mg	±10%
Isoflavones	50,00 mg	±10%
Moisture	6,01 g	±10%

*As amino acid chelate

An example of a nutritional composition of the food product per 15 g is shown in Table 8.

10

TABLE 8

Nutrient	Weight	Range	% Rda
Fat	10,28 g	±35%	-
Protein	0,98 g	±15%	-
Carbohydrate	2,64 g	±19%	-
Iron	3,16 mg	1,05 – 10,5 mg	32
Zinc	3,11 mg	1,03 – 10,3 mg	31

Selenium	20,00 µg	4 – 40 µg	50
Ascorbic acid	22,50 mg	4,5 – 45 mg	50
Beta-carotene	2,29 mg	±10%	
Alpha-carotene	1,79 mg	±10%	
Other carotenes	0,76 mg	±10%	
Retinol equivalents (RE)	300 - 1000	±25%	60-200*
Alpha-tocopherol	0,97 mg	±50%	2,10 as alpha-tocopherol equivalents (alpha-TE)
Tocotrienols	3,87 mg	±15%	
Isoflavones	7,50 mg	±10%	-
Total energy per portion = 448 kJ ±10%			

*Depends on conversion factor used for beta-carotene

i.e. 6 µg all-trans-beta-carotene = 1 µg of all-trans-retinol, or

2 µg all-trans-beta-carotene in oil = 1 µg of all-trans-retinol

- 5 A typical fatty acid composition in the food product is shown in Table 9.

TABLE 9

Fatty Acid	Composition (%)
14:0	1,25
16:0	40,03
16:1	0,16
18:0	4,83
18:1	38,32
18:2	14,07
18:3	0,73
20:0	0,31
20:1	0,13

22:0	0,09
24:0	0,11

One method of making the food product is described below.

Step one:

- 5 A micronutrient premix comprising iron fumarate, zinc amino acid chelate and selenium acid chelate as per Tables 5 and 6 was formed by mixing the ingredients until a homogenous mixture is obtained.

Step two:

- 10 Carotino™ fat CS35FV, stored at ambient temperature, was stirred or fluffed until a smooth texture was obtained. This step simplifies the blending process of step four.

Step three:

- 15 The micronutrient premix was mixed with approximately half of a measured amount of the soy flour, so that a uniform distribution of the micronutrient premix in the soy flour was obtained.

Step four:

- 20 The mixture obtained from step three was added to the fat from step two and mixed together to form a combined mixture with a smooth texture. The remainder of the measured soy flour was then mixed into the combined mixture. This step not only results in uniform distribution of the micronutrients in the fat, but also results in substantial micro-encapsulation of the micronutrients. This micro-encapsulation protects the micronutrients from oxidation and interaction with Vitamin C, thereby
25 prolonging the shelf life of the food product.

Step five:

- 30 Puratex™ 78150 sugar syrup, ascorbic acid and flavouring agents were mixed together in one container until a uniform distribution was obtained. The ascorbic acid and flavouring agents are water soluble, and as the Puratex™ 78150 contains about

23% water it is therefore an ideal carrier for the ascorbic acid and flavouring agents. As the Puratex™ 78150 is the only source of water in the food product, the end product has a low water content.

5 Step six:

The mixture obtained from step five was mixed with the mixture obtained from step four until a smooth consistency was obtained.

Steps one to six were carried out at ambient room temperature.

10

The mixing sequence and technique prevents an interaction among the components in the food product, particularly the micronutrients. For example, the sequence of steps two to five results in a safe and stable product.

15 Tests were conducted for microbiological activity in the food product kept at room temperature. The results showed no significant change in microbiological activity after 4 months of shelf life at room temperature.

The food product may have the following properties and advantages:

- 20 i) It is safe for consumption on a daily basis.
- ii) It has a relatively long shelf life of at least 4 months when kept at room temperature and is resistant to fungal growth.
- iii) It contains high levels of natural antioxidants which reduce the need for synthetic preservatives.
- 25 iv) It has a low water content which reduces the need for emulsifiers.
- v) It contains no hydrogenated fat (such as trans-fatty acids).
- vi) It contains added iron, zinc, selenium, and/or vitamin C (such as ascorbic acid) to alleviate nutrient deficiencies, for example, in children.
- vii) It is aflatoxin-free.

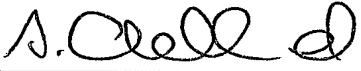
30

The food product may have the additional advantage of improving the general health, mental ability and school attendance in children who consume 15 g of the product

per day. A further advantage is that the food product has a desirable texture, stability and colour that may appeal to consumers.

The examples given herein are not to be construed as limiting to the scope of the invention. For example, although ascorbic acid is described as the source of vitamin C, sodium ascorbate, potassium ascorbate and the like could also be used. Similarly, any other suitable minerals or micronutrients could be used, and the quantities of the various micronutrients, vitamins and flavouring agents can obviously be varied according to specific needs in a particular market.

DATED THIS 25TH DAY OF FEBRUARY 2004



SPOOR & FISHER
APPLICANT'S PATENT ATTORNEYS